JUN 1 0 2014

K140521

510(k) Summary

ArthroCare® Corporation
TOPAZ® EZ Microdebrider Coblation® Wand
With Integrated Finger Switch

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

General Information

Submitter Name:	ArthroCare Corporation
Address	7000 West William Cannon Drive Austin, TX 78735
Contact Person:	Mitchell A. Dhority Vice President, Regulatory Affairs Phone: 512-358-5995 Fax: 512-895-1489
Date Prepared:	February 27, 2014

Device Name

Proprietary Name:	TOPAZ® EZ Microdebrider Coblation® Wand with Integrated Finger Switch
Regulation Name:	Electrosurgical cutting and coagulation device and accessories
Regulatory Class:	II
Product Code:	GEI
Regulation Number:	21 CFR 878.4400

Predicate Device

TOPAZ® Microdebrider Coblation® Wand with Integrated Finger Switch included in:

ArthroCare Topaz Wand, K080282 (cleared February 15, 2008)

Description

The TOPAZ® EZ Microdebrider Coblation® Wand with Integrated Finger Switch (Topaz EZ IFS) is a bipolar, sterile, high frequency electrosurgical device, which consists of a distal electrode tip composed of tungsten, an alumina ceramic spacer, stainless steel shaft, saline irrigation tubing and a molded handle with an integrated single finger switch used to activate the Wand. The handle connects proximally to the radiofrequency Controller via an electrical cable. The Topaz EZ IFS is only compatible with the ArthroCare Quantum Controllers.

Intended Use/Indications for Use

The TOPAZ® EZ Microdebrider Coblation® Wand with Integrated Finger Switch is indicated for debridement, resection, ablation, and coagulation of soft tissue and hemostasis of blood vessels in arthroscopic and orthopedic procedures:

Procedure	Body Structure as Described Below
Fasciotomy	Foot
Synovectomy	Foot
Tendonotomy	Knee, Wrist, Elbow, Ankle. Shoulder, Foot
Rotator Cuff Tendonotomy	Shoulder
Capsulotomy	Foot

Summary of Technological Characteristics

This Special 510(k) proposes modifications to the materials, dimensional specifications, and performance specifications of the ArthroCare Topaz Wand cleared under K080282. The indications for use, fundamental scientific technology, principle of operation, and sterilization methodology remain the same as in the previously cleared 510(k).

The following table summarizes the technological differences between the subject and predicate devices and describes the rationale for the change.

Parameter	Predicate Device: Topaz Wand (K080282)	Subject Device: TOPAZ EZ IFS Wand	Rationale for Change
Spacer Material	Thermal-Set Silicone Elastomer (Silicone)	Alumina	Facilitates consistency in manufacturability
Shaft Length	2.91 inches (74mm)	1.57 inches (40mm)	Length shortened based on user feedback (decreases the working distance between the user and the surgical site)
External Shaft Insulation Material	Nylon	Polyester	Material now used to insulate the shaft as opposed to also serving as the saline sheath
Saline Delivery (irrigant contacting material)	Nylon and stainless steel	Pebax and stainless steel	Provides saline delivery close to the tip of the wand and greater visibility for the surgeon
Shaft OD	0.032 ± .005" (.812 ± .13mm)	0.042 ± .005" (1.067 ± .13mm)	Increased stiffness of the shaft
Active Electrode Insulation Material	Polyimide	Pebax	Manufacturability
Shaft Y-Connector and Bushing	Separate components comprised of PVC and polycarbonate, respectively	Single integrated component comprised of polycarbonate	Cost savings and process improvement. Adhesive was increased to prevent the shaft from sliding within Y-connector.
Active/Return Electrode Insulator	N/A	Clear Pebax	Insulates electrodes; centers electrode components during manufacturing
Internal	N/A	Nylon	Holds cured adhesive to

Parameter	Predicate Device: Topaz Wand (K080282)	Subject Device: TOPAZ EZ IFS Wand	Rationale for Change
Reinforcement Tubing			facilitate bonding of electrodes during manufacturing
Labeling	Topaz IFS	Topaz EZ IFS	Proprietary name change. Instructions strengthened.

Summary of Non-Clinical Performance Data

Non-clinical performance testing verifies that the Topaz EZ IFS performs as intended and that no additional risks or hazards have been identified as a result of the changes described in this Special 510(k). As such, results from this testing support the determination that the Topaz EZ IFS is substantially equivalent to the predicate device. The following table lists the non-clinical testing performed and the results obtained in support of substantial equivalence.

Testing Type	Test Description	Result Supporting Substantial Equivalence
Verification Testing	• Visual Inspection • Dimensional Inspection • Hi-Pot Testing • Electrical Impedance • Saline Flow Rate • Controller Ablation Set Points • Finger Switch Actuation Testing • Ablation Testing • Shaft Stiffness • Axial Compression Force Testing	Both the Topaz EZ IFS and predicate device have substantially equivalent testing specifications and both performed within acceptance criteria. These results support that the Topaz EZ IFS and predicate device are substantially equivalent.
Biocompatibility Testing	• Cytotoxicity • Sensitization • Maximization	The Topaz EZ IFS and the predicate device are biocompatible. These results support that the Topaz EZ IFS and predicate device are substantially equivalent.
Electrical Safety Testing	Testing in accordance with IEC 60601-2-2:2009.	The Topaz EZ IFS and the predicate met all acceptance criteria in accordance with IEC 60601-2-2: 2009. These results support that the Topaz EZ IFS and predicate device are substantially equivalent.

Clinical Data

No clinical data are included in this submission

Summary

The Topaz EZ IFS is substantially equivalent to the predicate Topaz Wand (K080282). Both the subject and predicate devices have the same indications for use and utilize the same fundamental scientific technology. All product performance testing demonstrates that the Topaz EZ IFS performs as intended and has acceptable mechanical properties when used in accordance with its labeling. The minor differences between the Topaz EZ IFS and the predicate device do not raise any new questions of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 10, 2014

ArthroCare Coporation
Mr. Mitchell A. Dhority
Vice President, Regulatory Affairs
7000 West William Cannon Drive
Austin, Texas 78735

Re: K140521
Trade/Device Name: TOPAZ® EZ Microdebrider Coblation® Wand with Integrated Finger Switch
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: May 13, 2014
Received: May 14, 2014

Dear Mr. Dhority:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(If known)*
K140521

Device Name
TOPAZ® EZ Microdebrider Coblation® Wand with Integrated Finger Switch

Indications for Use *(Describe)*
The TOPAZ® EZ Microdebrider Coblation® Wand with Integrated Finger Switch is indicated for debridement, resection, ablation, and coagulation of soft tissue and hemostasis of blood vessels in arthroscopic and orthopedic procedures:

Procedure	Body Structure
Fasciotomy	Foot
Synovectomy	Foot
Tendonotomy	Knee, Wrist, Elbow, Ankle, Shoulder, Foot
Rotator Cuff Tendonotomy	Shoulder
Capsulotomy	Foot

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Joshua C. Nipper -S

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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PRAStaff@fda.hhs.gov

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